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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,849	05/23/2001	Jerome O. Cantor	C35795/125237	1932

7590 07/23/2004
BRYAN CAVE LLP
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NEW YORK, NY 10104

EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/863,849

Applicant(s)

CANTOR ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-12, 14-24, 26, 27 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 31-33 is/are allowed.
- 6) ☒ Claim(s) 5-12, 14-24, 26, 27, 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 02/5/04.

The amendment filed 02/5/04 affects the application, 09/863,849 as follows:

1. Claims 1-4, 13, 25, 28, and 29 have been canceled. Claims 5, 6, 14-21, 26, 30 have been amended. New claims 34-36 have been added. This leaves claims 5-12, 14-24, 26, 27, 30-33.
2. Applicant responds to the 102 and 103 rejections by canceling, amending and adding new claims as stated above.

The responsive to applicants' arguments is contained herein below.

Claims 5-12, 14-24, 26, 27, 30-33 are pending in application

Election/Restrictions

Newly submitted claims 34-36 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 34-36 recites a method of lung treatment. However, the said method of claim 34-36 was not originally examined, is a different or distinct invention which would involve a different search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 34-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Consequently, It should be noted that the amended claims 6-12 and 14-20 which dependent on the newly submitted claims 34-36 are not examined since they depend on claims 34-36 which are withdrawn from consideration as being directed to a non-elected invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 26, 27, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,633,003) in view of Ganderton et al. (US 5,376,386), both of record.

In claim 21, applicant claims "a method of administering to a mammal a therapeutic formulation, the formulation comprising a polysaccharide and a drug, at a selected dose via a respiratory tract, comprising: formulating a solution comprising the polysaccharide to achieve a controlled polysaccharide size of between about 50,000 and 1.5×10^6 Daltons at a concentration of less than about 5 mg/ml (w/w) of the polysaccharide; producing an aerosol of the solution such that a droplet of the aerosol has a median mass distribution size of between about 0.5 to about 10 microns; and delivering said aerosol into said respiratory tract by inhalation." Claims 22-24 and 26 which are drawn to specific polysaccharides of specific molecular weights, are also encompassed by the aforementioned rejection.

Cantor discloses applicant's method of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide (hyaluronic acid) that binds to elastic fibers, thereby preventing enzymes (like elastase) or other injurious agent from contacting and damaging said elastic fibers" (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor method also includes the delivery via a route

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aerosol inhalation. Furthermore, Cantor teaches that the aerosol can be generated by a nebulizer (see abstract).

Ganderton et al. disclose an inhalant wherein the carrier can be a polysaccharide and the drug (a bronchodilator) can include terbutaline. (see claim 1 and col. 4, lines 26-36).

The difference between applicants' claimed method and the method of Cantor is that Cantor does not disclose the concentration, molecular weight or particle size of the polysaccharide and cantor does not use a drug. However, Ganderton et al. disclose that a polysaccharide and bronchodilator drugs including terbutaline, can be used as an inhalant. (see claim 1 and col. 4, lines 26-36). In addition, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising a polysaccharide.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Cantor in view of Ganderton et al., and to use a composition comprising different concentration, molecular weight or particle size of the polysaccharide in combination with a bronchodilator drug disclosed by Ganderton et al., which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the respiratory disorder).

One having ordinary skill in the art would have been motivated, to use the process of Cantor in view of Ganderton et al., and to use a composition comprising different concentration, molecular weight or particle size of the polysaccharide in combination with a bronchodilator drug disclosed by Ganderton et al., which has the same utility as Cantor's composition and is been administered by the same method of delivery, depending on need (like the severity of the

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respiratory disorder). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Allowable subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 31-33 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. Claims 31 and 33 to be unobvious over the prior art of record and may be allowable provided that they do not depend on a rejected claim, rewritten in acceptable form and does not include any new subject matter. The present invention relates to a process of treating respiratory disorders which comprises administering to a mammal a therapeutically effective amount of a polysaccharide that binds to elastic fibers, thereby preventing enzymes, oxidants, or other injurious agent from contacting and damaging said elastic fibers. The invention further involves the administering the polysaccharide together with specific drugs. The very relevant prior art documents to this invention (US 5,633,003 and US 5,376,386) disclose a method of treating respiratory disorders which comprises administering a polysaccharide and drugs to a mammal.

However, though the process of the present invention is similar to that disclosed in the prior art document, the composition of claims 31-33 comprises a polysaccharide of specific molecular weight and concentration together with a fluorocarbon propellant, whereas the composition of the prior art contains a polysaccharide of different molecular weight and concentration, and lacks the presence of the said fluorocarbon propellant. Furthermore,

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applicant's composition is unobvious to those of the prior art, and that are not suggested or taught by the prior art document.

Response to Amendment

Applicant's arguments with respect to claims 1-4 and 17-28 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be

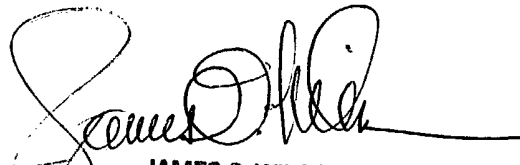
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reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

July 12, 2004.



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600